II. REMARKS

Patentability Remarks

35 U.S.C. §112, First Paragraph, with regard to written description.

Claims 38-51 and 53-62 were rejected under 35 U.S.C. 112, 1st paragraph, for lack of written description of claimed subject matter.

(1) Claims 51 and 62 were rejected for lack of description in the specification of "intravascular" administration. The term "intravascular" has been deleted from the claims and is replaced by "intravenous," support for which is found in the specification, for example, in lines 12-15 on page 85.

(2) Claims 50 and 57 were rejected on the grounds that the specification does not describe a method wherein the IgE mediated allergic disorder that is treated is an anaphylactic reaction or bronchitis. The treatment of an anaphylactic reaction or bronchitis by the claimed method is described in the specification; for example, on page 81, lines 15 and 21.

(3) The claims were rejected on the grounds that the specification does not describe the method of claims 38 and 47 in which the anti-human CD23 monoclonal antibody is one that competes for binding to CD23 with an antibody comprising the CDRs of the light and heavy chains of antibody 6G5 or of antibody 5E8. The applicants submit that the written description of the claimed invention provided by the specification complies with the requirements of 35 U.S.C. 112, 1st paragraph. As stated in the Federal Register (vol. 66, No. 4, pp. 1099, 1104, January 5, 2001), the essential goal of the written description requirement of 35 U.S.C. 112, 1st paragraph, is to clearly convey that an applicant has invented the subject matter which is claimed (citing In re Barker, 559 F.2d 588, 592, n.4; 194 USPQ 470, 473, n.4 (CCPA 1977)) . To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention (citing Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 68; 119 S. Ct. 304, 312; 48 USPQ2d 1641, 1647 (1998); Regents of the Univ. of California v. Eli Lilly, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406(Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). The specification expressly states that the present invention includes the use of antibodies that compete with the primate anti-human CD23 monoclonal antibodies 5E8 and 6G5 for binding to CD23 (p. 21, lines 19-21). The specification discloses the polypeptide sequences of the variable regions of the light and heavy chains of primate antibodies 6G5 and 5E8, and identifies the three CDR sequences of

each antibody polypeptide that fold to form the CD23-binding sites (see pages 50-56 and 59-63). The specification also describes known methods by which one of ordinary skill in the art can make antibodies that compete with the primate anti-human CD23 monoclonal antibodies 5E8 and 6G5 for binding to CD23. Such methods are described in the specification as comprising combining the CD23-binding portions of a non-human antibody with the constant and framework portions of a human antibody (e.g., by primatization® or CDR grafting) to produce chimeric or humanized antibodies that have the antigen-binding specificity of the non-human antibody (see pp. 12-13 and 16-17). Moreover, the specification expressly describes using such methods to make chimeric antibodies having the antigen-binding portions of primate antibodies 6G5 and 5E8 (e.g., see p. 17, lines 4-9). A person of ordinary skill in the art at the time the priority application was filed would have therefore have understood the specification as describing methods for making and using antibodies that compete for binding to CD23 with an antibody comprising the CDRs of the light and heavy chains of antibody 6G5 or of antibody 5E8, e.g., as a humanized or a chimeric antibody, and so would have reasonably concluded that the inventors had possession of the claimed invention. Therefore, withdrawal of the rejection of the claims under 35 U.S.C. 112, 1st paragraph, for lack of written description is respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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